REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-34 are pending in the present application. Claims 1, 6-10, and 14-28 have been withdrawn from consideration. Claims 2-4, 11-13 and 29-34 are subject to examination.

Claims 2-4, 11-13, 30, 32 and 34 have been amended to more particularly point out and distinctly claim the present invention. Claims 2-4 and 29-34 are directed to a device for separating CD4-positive cells. Claims 11-13 are directed to a method for separating or detecting human CD4-positive cells. Both the claims directed to the device and method recite that the antibodies are capable of binding to a water-insoluble carrier in the form of fiber. Support for this recitation may be found in the present specification from pages 28 to 36.

In the outstanding Official Action, claims 2-4, 11-13 and 29-34 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite for failing to particularly point and distinctly claim the subject matter which applicant regards as the invention. It is believed that the present amendment obviates this rejection.

The outstanding Official Action alleged that the term "a device for separating CD4-positive cells using an antibody" was indefinite for not reciting any structural features. However, as noted above, claims 2-4 have been amended to recite that the antibody binds to a water-insoluble carrier in the form of fiber. Thus, it is believed that claims 2-4 are definite to one of ordinary skill in the art.

The outstanding Official Action rejected claims 2, 30, 32, and 34 because the Markush group of antibodies was allegedly indefinite. In the interest of advancing prosecution, the Markush groups found in claims 2, 30, 32 and 34 have been amended and. It is believed that claims 2, 30, 32 and 34 are definite to one of ordinary skill in the art.

The claims were also rejected for containing the recitation "combinations thereof". The Official Action alleged that this recitation was unclear. However, the claims have been amended to further clarify this term. Thus, it is believed that the present amendment obviates this rejection.

Claims 11-13 were rejected for allegedly setting forth an incomplete method. However, as noted above, claims 11-13 have been amended to recite a method for separating or detecting human CD4-positive cells. The method comprises contacting a cell suspension comprising CD4-positive cells with said water-insoluble carrier, separating said cell suspension and said

carrier, and obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface.

Claims 32 and 34 were rejected for allegedly reciting more members of a Markush group than recited in the corresponding independent claim. However, as noted above, claims 32 and 34 have been amended to obviate the contentions pertaining to the Markush groups.

Thus, in view of the above, it is believed that the claimed invention is definite to one of ordinary skill in the art.

In the outstanding Official Action claims 10 and 11 were rejected under 35 USC 102(b) as allegedly being anticipated by GORMAN et al. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that claim 2 was devoid of any structural features other than the antibody. As to claim 11, the Official Action alleged that the claim did not recite proper method steps. However, as noted above, claim 2 has been amended to recite a device that comprises an antibody that binds to CD4 molecules and a water-insoluble carrier in the form of fiber. Claim 11 has been amended to recite method steps of contacting a cell suspension comprising CD4-positive cells with said water-insoluble carrier, separating said cell suspension and said carrier, and obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface. Thus, it is believed that the claimed invention is

directed to a device or method for separating CD4-positive cells, which is simple, rapid and cost-effective.

Applicants respectfully submit that GORMAN et al. fail to disclose or suggest the claimed device and method. GORMAN et al is directed to anti-CD3 antibodies having CDR regions from a rodent antibody grafted into a human framework. Thus, it is believed that GORMAN et al Fail to disclose or suggest a device for separating CD4-positive cells comprising an antibody that binds to CD4 molecules and a water-insoluble carrier. As a result, it is believed that GORMAN et al. fail to anticipate or render obvious claims 2 and 11.

Claims 2 and 11 were further rejected under 35 USC 102(e) as allegedly being anticipated by BURKLEY et al. This rejection is respectfully traversed.

As noted above, the Official Action alleged that claim 2 is devoid of any structural features other than an antibody per se. Moreover, the Official Action alleged that the method claims did not recite proper method steps. However, as noted above, claims 2 and 11 have been amended to more particularly point out and distinctly claim the present invention.

It is believed that BURKLEY et al. fail to disclose or suggest a device comprising an antibody, a CD4 molecule and a water-insoluble carrier. Moreover, it is believed that BURKLEY et al. fail to disclose or suggest a method for separating or detecting human CD4-positive cells comprising contacting a cell

suspension comprising CD4-positive cells with said water-insoluble carrier, separating said cell suspension and said carrier, and obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface. Indeed, the Patent Office does not contend otherwise.

Applicants believe that the Official Action fails to meet is burden is showing that it would be apparent to one of ordinary skill in the art that the chimeric and humanized antibodies taught by BURKLY et al could be used in the manner as set forth in the claimed invention. Indeed, it is believed that the Official Actions fails to present any evidence that antibodies taught by BURKLY et al may be used in accordance with the claimed invention.

Thus, it is believed that BURKLEY et al. fails to anticipate or render obvious claims 2 and 11.

Claims 2-3 and 11-12 were rejected under 35 USC 102(b) as allegedly being anticipated by HINTON et al. This rejection is respectfully traversed.

The claimed invention is directed to a device and method for separating or detecting CD4-positive cells. The present invention does not require any special or large/expensive devices unlike FACS method or a method utilizing avidin-coated particles/magnetic beads.

While the Official Action alleges that the V-kappa chain sequence and H-chain sequence shown in Figures 2 and 3 of

HINTON, respectively, show the sequence identification numbers of the claimed invention, applicants traverse this assertion. It is believed that the amino acids are distinct and non-obvious.

The amino acids of the present invention and HINTON et al. are shown as follows:

ID NO:6 Gln-Gln-Ser-Ser-Glu-Asp-Pro-Pro-Thr
HINTON Gn-Gln-Ser-Tyr-Glu-Asp-Pro-Pro-Thr

ID NO:2 Glu-Ile-Tyr-Pro-Gly-Ser-Gly-Ser-Ala-Tyr-Tyr-Asn-Glu-Met-Phe-Lys-Gly
HINTON Glu-Thr-Tyr-Thr-Gly-Ser-Gly-Ser-Ser-Tyr-Tyr-Asn-Glu-Lys-Phe-Lys-Gly

ID NO:3 Arg-Gly-Thr-Gly-Thr-Gly-Phe-Ala-Tyr
HINTON Arg-Gly-Lys-Gly-Thr-Gly-Phe-Ala-Phe

In view of the above, it is believed to be apparent that the sequences are distinct. As the Examiner is aware, the binding ability of an antibody to antigen may be affected significantly by even the smallest of mutations in CDR regions. As a result, it is believed to be apparent that the sequences of the present invention are clearly different from those set forth in HINTON. That is, the antibodies of the present invention are distinct and non-obvious in view of HINTON'S antibody.

Thus, it is believed that HINTON et al. fails to anticipate or render obvious the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 2-4, 11-13, and 29-34, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

YOUNG & THOMPSON

Philip A. DuBois, Reg. No. 50,696

745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297

June 5, 2003

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 2 has been amended as follows:

2. (amended) A device for separating CD4-positive cells, [using] comprising:

an antibody selected from the group consisting of a chimera antibody, a single chain antibody [which] and combinations thereof, wherein said antibody binds to CD4 molecules, [or combinations thereof] and wherein said antibody is bound to a water-insoluble carrier in the form of fiber.

Claim 3 has been amended as follows:

3. (amended) A device for separating CD4-positive cells, [using] comprising a chimera antibody, wherein the antibody comprises an H chain variable region of which CDR-1 is an amino acid sequence represented by Sequence ID No. 1 in the Sequence Listing, CDR-2 is an amino acid sequence represented by Sequence ID NO. 2 in the Sequence Listing, and CDR-3 is an amino acid sequence represented by Sequence ID No. 3 in the Sequence Listing, an L chain variable region of which CDR-1 is an amino acid sequence represented by Sequence ID No. 4 in the Sequence Listing, CDR-2 is an amino acid sequence represented by Sequence ID No. 5 in the Sequence Listing, and CDR-3 is an amino acid sequence represented by Sequence ID No. 6 in the Sequence

Listing, and an Fc region of a human type, and wherein said chimera antibody is bound to a water-insoluble carrier in the form of fiber.

Claim 4 has been amended as follows:

4. (amended) A device for separating CD4-positive cells, [using] comprising a single chain antibody, wherein the antibody comprises an H chain variable region of which CDR-1 is an amino acid sequence represented by Sequence ID No. 1 in the Sequence Listing, CDR-2 is an amino acid sequence represented by Sequence ID NO. 2 in the Sequence Listing, and CDR-3 is an amino acid sequence represented by Sequence ID No. 3 in the Sequence Listing, and an L chain variable region of which CDR-1 is an amino acid sequence represented by Sequence ID No. 4 in the Sequence Listing, CDR-2 is an amino acid sequence represented by Sequence ID No. 5 in the Sequence Listing, and CDR-3 is an amino acid sequence represented by Sequence ID No. 6 in the Sequence Listing, and wherein said single chain antibody is bound to a water-insoluble carrier in the form of fiber.

Claim 11 has been amended as follows:

11. (amended) A method for separating or detecting human CD4-positive cells using an antibody selected from the group consisting of a chimera antibody, a single chain antibody, and combinations thereof, wherein said antibody is bound to a

water-insoluble carrier in the form of fiber directly or indirectly, comprising:

contacting a cell suspension comprising CD4-positive cells with said water-insoluble carrier,

separating said cell suspension and said carrier, and

obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface

[an antibody selected from a chimera antibody, a single chain antibody which bind to CD 4 molecules or molecules, or combinations thereof].

Claim 12 has been amended as follows:

12. (amended) A method for separating or detecting human CD4-positive cells, [comprising] using a chimera antibody to CD4 molecules, wherein the antibody comprises an H chain variable region of which CDR-1 is an amino acid sequence represented by Sequence ID No. 1 in the Sequence Listing, CDR-2 is an amino acid sequence represented by Sequence ID NO. 2 in the Sequence Listing, and CDR-3 is an amino acid sequence represented by Sequence ID No. 3 in the Sequence Listing, an L chain variable region of which CDR-1 is an amino acid sequence represented by Sequence ID No. 4 in the Sequence Listing, CDR-2 is an amino acid sequence represented by Sequence ID No. 5 in the Sequence Listing, and CDR-3 is an amino acid sequence represented by

Sequence ID No. 6 in the Sequence Listing, and an Fc region of a human type, comprising:

contacting a cell suspension comprising CD4-positive cells with said water-insoluble carrier,

separating said cell suspension and said carrier, and

obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface.

Claim 13 has been amended as follows:

13. (amended) A method for separating or detecting human CD4-positive cells, comprising using a single chain antibody to a CD4-molecule, wherein the antibody comprises an H chain variable region of which CDR-1 is an amino acid sequence represented by Sequence ID No. 1 in the Sequence Listing, CDR-2 is an amino acid sequence represented by Sequence ID NO. 2 in the Sequence Listing, and CDR-3 is an amino acid sequence represented by Sequence ID No. 3 in the Sequence Listing, and an L chain variable region of which CDR-1 is an amino acid sequence represented by Sequence ID No. 4 in the Sequence Listing, CDR-2 is an amino acid sequence represented by Sequence ID No. 5 in the Sequence Listing, and CDR-3 is an amino acid sequence represented by Sequence ID No. 6 in the Sequence Listing, comprising:

contacting a cell suspension comprising CD4-positive cells with said water-insoluble carrier,

separating said cell suspension and said carrier, and

obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface.

Claim 30 has been amended as follows:

30. (amended) The device for separating cells according to claim 2, wherein the antibody selected from the group consisting of a chimera antibody, a single chain antibody, [or] and combinations thereof is bound to an active group of a polypropylene nonwoven fabric reacted with a haloacetaminomethylating agent.

Claim 32 has been amended as follows:

32. (amended) The device for separating cells according to claim 3, wherein the antibody [selected from a chimera antibody, a single chain antibody or combinations thereof] is bound to an active group of a polypropylene nonwoven fabric reacted with a haloacetaminomethylating agent.

Claim 34 has been amended as follows:

34. (amended) The device for separating cells according to claim 4, wherein the antibody [selected from a chimera antibody, a single chain antibody or combinations thereof] is bound to an active group of a polypropylene nonwoven fabric reacted with a haloacetaminomethylating agent.